DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-368]

Definition of "Cannabimimetic Agents" and Assignment of an Administration Controlled Substances Code Number for all "Cannabimimetic Agents"

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: On July 9, 2012, the President signed into law the Synthetic Drug Abuse Prevention Act of 2012. The Synthetic Drug Abuse Prevention Act of 2012 included a definition of "cannabimimetic agents" that are controlled under schedule I. The Drug Enforcement Administration is proposing this rule to address the broader definition of "cannabimimetic agents," identify 18 additional substances that meet the definition, and consolidate most existing administration controlled substances code numbers (drug codes) into a single drug code number for substances that meet this definition. The listing for two schedule I "cannabimimetic agents" that are under international control, JWH-018 and AM2201, will be moved to the "hallucinogens" paragraph of schedule I in order to retain the existing drug codes for these two substances to facilitate quota and international reporting requirements. While the 18 additional substances are already controlled under schedule I because they meet the definition of "cannabimimetic agents," this proposed rule establishes a single new drug code number for these and most other substances meeting this definition. This single drug code will simplify the registration and recordkeeping requirements for any "cannabimimetic agents" that the Drug Enforcement Administration may register persons to handle.

DATES: Comments must be submitted electronically or postmarked on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-368" on all electronic and written correspondence, including any attachments.

- *Electronic comments:* DEA encourages commenters to submit all comments electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to https://www.regulations.gov and follow the on-line instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number. Submitted comments are not instantaneously available for public view on *regulations.gov*. If you have received a Comment Tracking Number, you have submitted your comment successfully and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA FR Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make comments available, unless reasonable cause is given, for public inspection online at *https://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want DEA to make it publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want DEA to make it publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

DEA will generally make available in publicly redacted form comments containing personal identifying information and confidential business information identified, as directed above. If a comment has so much confidential business information that DEA cannot effectively redact it, DEA may not make available publicly all or part of that comment. Comments posted to *https://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as confidential as directed above.

An electronic copy of this document is available at *https://www.regulations.gov* for easy reference.

Legal Authority

On July 9, 2012, the Synthetic Drug Abuse Prevention Act of 2012 (SDAPA), Pub. L. 112-144, Title XI, Subtitle D, became effective. SDAPA amended the CSA by legislatively placing "cannabimimetic agents" in schedule I. Pub. L. 112-144, Title XI, Subtitle D, Section 1152; 21 U.S.C. 812(d). On January 4, 2013, DEA published a final rule that added paragraph (g) to 21 CFR 1308.11 with the title "cannabimimetic agents," and assigned unique administration controlled substances code numbers (drug codes) for 15 substances included in SDAPA that met this definition. 78 FR 664.

DEA is proposing this rule to make technical, organizational, and conforming amendments to paragraph (g). This rule would make no change in the current and continuing schedule I status for all of the substances discussed in this rule. This action proposes to:

- incorporate the structural and pharmacological definition of "cannabimimetic agents" found in 21 U.S.C. 812(d) into paragraph (g),
- list 18 additional substances that meet the structural and pharmacological definition of "cannabimimetic agents" in paragraph (g),
- consolidate 13 of the 15 existing drug codes previously assigned to "cannabimimetic agents" and establish a single drug code for most substances that meet this definition, and
- move two substances (JWH-018 and AM2201) from paragraph (g) to paragraph (d) and retain the existing drug codes (7118 and 7201, respectively) to facilitate quota and international reporting requirements.

DEA has collected data for 18 additional substances that meet the structural and pharmacological definition in accordance with SDAPA: AM-1220; AM-2233; EAM-

2201; JWH-098; JWH-184; JWH-193; JWH-210; MAM-2201; JWH-007; JWH-022; JWH-147; JWH-302; JWH-307; JWH-412; WIN 55,212-2; CP-55,940; CP-47,497 C6 homolog; and CP-47,497 C9 homolog.

Two of the substances (JWH-018 and AM2201) that are currently listed in 21 CFR 1308.11(g) are also listed in Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention).[1] In order to continue to establish aggregate production quota and grant individual manufacturing and procurement quota to DEA-registered manufacturers of JWH-018 and AM2201, and report these data as required under Article 16 the 1971 Convention, DEA proposes to move the listing for these two substances from 21 CFR 1308.11(g) to 21 CFR 1308.11(d). With the proposal to assign all substances in 21 CFR 1308.11(g) a single drug code, moving the listing of these two drugs will maintain their current drug codes (7118 and 7201, respectively) and allows DEA to continue collecting data reported to the International Narcotics Control Board (INCB) on Form P.[2]

Regulatory Analyses

Executive Orders 12866 and 13563 (Regulatory Planning and Review; Improving Regulation and Regulatory Review)

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. This proposed rule is not a significant regulatory action under E.O. 12866. All of the substances listed in this proposed rule are already listed or defined as controlled substances in the United States under schedule I. In this proposed rule, DEA is proposing technical, organizational, and conforming amendments to its regulations to incorporate definitions found in 21 U.S.C. 812(d), list

[1] On March 13, 2015, the Commission on Narcotic Drugs decided to include JWH-018 and AM2201 in Schedule II of the Convention on Psychotropic Substances of 1971.
[2] The current form can be downloaded from the INCB website: www.incb.org, under “Psychotropic Substances”, Toolkit: “Form P”.

additional "cannabimimetic agents" that meet these definitions, and simplify drug codes assigned to "cannabimimetic agents." These proposed changes only apply to substances that are already listed or defined as schedule I controlled substances. Creating listings for these substances and modifying drug codes will not alter the status of any of these substances as schedule I controlled substances. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Paperwork Reduction Act of 1995

This proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), has reviewed this proposed rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA proposes technical, organizational, and conforming amendments to its regulations to incorporate definitions found in 21 U.S.C. 812(d), list additional "cannabimimetic agents" that meet these definitions, and simplify drug codes assigned to "cannabimimetic agents." These proposed changes only apply to substances that are already listed or defined as schedule I controlled substances. If finalized, this action would not impose any new regulatory controls or new administrative, civil, and/or criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle "cannabimimetic agents."

Anyone currently handling "cannabimimetic agents" must already be registered with DEA and have all security and other handling processes in place, resulting in minimal impact to their operations. Therefore, DEA estimates the cost of this rule, in form of lost sales, if any, on small entities is minimal. DEA welcomes any public comment regarding this estimate.

Because of these facts, this proposed rule will not, if promulgated, result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.)* that this proposed action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for

inflation) in any 1 year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308 - SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

AUTHORITY: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. In § 1308.11:

a. Add paragraphs (d)(102) and (103); and

b. Revise paragraph (g).

The additions and revision read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(102) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678) 7118

(103) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201).....7201

* * * * *

(g) *Cannabimimetic agents*. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Cannabimimetic agents - 7000.

(2) In this paragraph (g), the term *cannabimimetic agents* means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(3) The definition in this paragraph (g) includes, but is not limited to, the following substances:

(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);

(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);

(iii) 1-butyl-3-(1-naphthoyl)indole (JWH-073);

(iv) 1-hexyl-3-(1-naphthoyl)indole (JWH-019);

(v) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

(vi) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

(vii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);

(viii) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);

(ix) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);

(x) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

(xi) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4);

(xii) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8);

(xiii) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203);

(xiv) (1-((1-methylpiperidin-2-yl)methyl)-1*H*-indol-3-yl)(naphthalen-1-yl)methanone (AM-1220);

(xv) (2-iodophenyl)(1-((1-methylpiperidin-2-yl)methyl)-1*H*-indol-3-yl)methanone (AM-2233);

(xvi) (4-ethylnaphthalen-1-yl)(1-(5-fluoropentyl)-1*H*-indol-3-yl)methanone (EAM-2201);

(xvii) (4-methoxynaphthalen-1-yl)(2-methyl-1-pentyl-1*H*-indol-3-yl)methanone (JWH-098);

(xviii) 3-((4-methylnaphthalen-1-yl)methyl)-1-pentyl-1*H*-indole (JWH-184);

(xix) (4-methylnaphthalen-1-yl)(1-(2-morpholinoethyl)-1*H*-indol-3-yl)methanone (JWH-193);

(xx) (4-ethylnaphthalen-1-yl)(1-pentyl-1*H*-indol-3-yl)methanone (JWH-210);

(xxi) (1-(5-fluoropentyl)-1*H*-indol-3-yl)(4-methylnaphthalen-1-yl)methanone (MAM-2201);

(xxii) (2-methyl-1-pentyl-1*H*-indol-3-yl)(naphthalen-1-yl)methanone (JWH-007);

(xxiii) naphthalen-1-yl(1-(pent-4-en-1-yl)-1*H*-indol-3-yl)methanone (JWH-022);

(xxiv) (1-hexyl-5-phenyl-1*H*-pyrrol-3-yl)(naphthalen-1-yl)methanone (JWH-147);

(xxv) 2-(3-methoxyphenyl)-1-(1-pentyl-1*H*-indol-3-yl)ethan-1-one (JWH-302);

(xxvi) (5-(2-fluorophenyl)-1-pentyl-1*H*-pyrrol-3-yl)(naphthalen-1-yl)methanone (JWH-307);

(xxvii) (4-fluoronaphthalen-1-yl)(1-pentyl-1*H*-indol-3-yl)methanone (JWH-412);

(xxviii) (5-methyl-3-(morpholinomethyl)-2,3-dihydro-[1,4]oxazino[2,3,4-*hi*]indol-6-yl)(naphthalen-1-yl)methanone (WIN 55,212-2);

(xxix) 2-(5-hydroxy-2-(3-hydroxypropyl)cyclohexyl)-5-(2-methyloctan-2-yl)phenol (CP-55,940);

(xxx) 2-(3-hydroxycyclohexyl)-5-(2-methylheptan-2-yl)phenol (CP-47,497 C6 homolog); and

(xxxi) 2-(3-hydroxycyclohexyl)-5-(2-methyldecan-2-yl)phenol (CP-47,497 C9 homolog).

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on March 29, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Scott Brinks,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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